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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/299,139	04/23/1999	JEFFREY BROWNING	A013	2882

7590 10/23/2002
BIOGEN INC.
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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/23/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/299,139

Applicant(s)

BROWNING ET AL.

Examiner

Christopher H Yaen

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-94 is/are pending in the application.
- 4a) Of the above claim(s) 61-70, 79-83 and 91-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-56, 58-60, 71-78 and 84-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in Paper No. 17 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 51-94 are pending, claims 61-70, 79-83, and 91-94 are withdrawn from consideration as being drawn to a non-elected invention. Therefore, claims 51-56, 58-60, 71-78, and 84-90 are examined on the merits.
3. This application contains claims 61-70, 79-83, and 91-94 drawn to an invention nonelected in Paper No. 17. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

4. Claims 53, 58-60, 71-78, and 84-90 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Regarding claims 53, 75, 86, and dependent claims thereof, in the recitation of the term "functional", it is unclear as to the extend of functionality required from the amino acid sequence.

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6. Regarding claims 71 and dependent claims thereof, in the recitation of the phrase "effective amount", it is unclear as to the amount of soluble LT- β -R required to inhibit signaling (i.e. what amount is considered effective?).
7. Regarding claim 84 and dependent claims thereof, in the recitation of the term "association", it is unclear as to the type of "association" intended from the immune complexes.
8. Claims 51-60, 71-78, and 84-90 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting a humoral response comprising the administration of a LT- β -R-Ig fusion, does not reasonably provide enablement for a method of inhibiting a humoral response or a method of inhibiting LT- β -R signaling comprising the administration of a soluble LT- β -R. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276

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(CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The claims of the instant invention are drawn to a method of inhibiting a humoral response in an animal comprising the administration of a soluble LT- β -R, a method of inhibiting the LT- β -receptor signaling through the administration of soluble LT- β -R, and a method of disrupting the association of immune complexes and B cell follicles comprising the administration of LT- β -R.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that LT- β -R-Ig proteins are capable of inhibiting Th1 cell mediated immune responses (U.S. Pat No. 6,403,087), that LT- β -R-Ig proteins are capable of altering delayed type hypersensitivity (U.S. Pat No. 5,925,351), and the blocking of Lt $\alpha\beta$ /lymphotoxin β receptor interaction by the presence of LT- β -R-Ig (Ettinger *et al* PNAS USA 1996 Nov; 93:13102-13107).

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The amount of direction or guidance present and the presence or absence of working examples: The working examples of the instant application discloses the capability of LT- β -R-Ig proteins to disrupt humoral responses, however, no where in the specification does it teach to one of skill in the art how to disrupt or inhibit a humoral response through the administration of a soluble LT- β -R. Furthermore, the specification is devoid of any explanation of detailed example showing how the administration of soluble LT- β -R is capable of inhibiting the signaling of LT- β -R.

The breadth of the claims and the quantity of experimentation needed: Given the lack of a detailed working example for the inhibition of a humoral response and the inhibition of LT- β -R signaling, given the fact that the art solely shows T-cell response, and absent sufficient teachings in the art that show the capability to inhibit a humoral response and LT- β -R signaling, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

9. No claim is allowed. Because of the newly cited rejection made in the instant office action, this action is made **NON-FINAL**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-


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308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
October 21, 2002


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